



IAP4 Rec'd PCT/PTO 12 JAN 2006

PATENT

Docket No. 25401-42

CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop PCT; Commissioner for Patents; P.O. Box 1450; Alexandria, Virginia 22313-1450 on

January 9, 2006  
Bernie S Dole

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Michael Mahler : Paper No.:

Serial No.: 10/551,636 : Group Art Unit:

Filing Date: September 30, 2005 : Examiner:

For: **Analytical Method and Kit Thereof**

INFORMATION DISCLOSURE STATEMENT

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

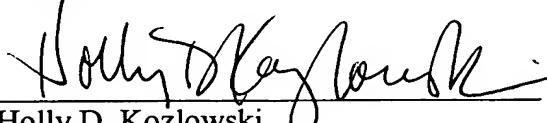
Dear Sir:

In accordance with the provisions of 37 C.F.R. §§ 1.56 and 1.97-1.98, Applicant cites the references listed on the attached Form PTO-1449. Copies of the non-U.S. patent references are enclosed.

Since the present statement is submitted before the mailing of a first Office Action on the merits, no statement or fee under 37 C.F.R. §1.97 is required (37 C.F.R. §1.97(b)(1)).

Please charge any fee required in connection with this Statement to Deposit Account 04-1133.

Respectfully submitted,



Holly D. Kozlowski  
Registration No. 30,468  
Attorney for Applicant(s)  
DINSMORE & SHOHL LLP  
1900 Chemed Center  
255 East Fifth Street  
Cincinnati, Ohio 45202  
(513) 977-8568

02 10 13 2006

**FORM PTO - 1449**  
**LIST OF PATENTS AND PUBLICATIONS**  
**FOR APPLICANT'S INFORMATION**  
**DISCLOSURE STATEMENT**
**ATTY DOCKET:** 25401-42  
**APPLICANT:** Michael Mahler  
**FILING DATE:** September 30, 2005  
**FOR:** Analytical Method and Kit Thereof

**SERIAL NO.:** 10/551,636  
**GROUP:**
**UNITED STATES LETTERS PATENT**

Exr. Init.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS

**OTHER ART (INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)**

aa	Abuaf, N., Johanet, C., Chretien, P., Absalon, B. I., Homberg, J. C., Buri, J. F., "Detection of autoantibodies to Sm antigen in systemic lupus erythematosus by immunodiffusion, ELISA and immunoblotting: variability of incidence related to assays and ethnic origin of patients", <i>European Journal of Clinical Investigation</i> 1990 20(4) pp 354-9
ab	Arbuckle, M. R., Reichlin, M., Harley, J. B., James, J. A., "Shared early autoantibody recognition events in the development of anti-Sm B/B in human lupus", <i>Scandinavian Journal of Immunology</i> , 1999 50(5) pp 447-455.
ac	Arnett, F. C., Edworthy, S. M., Bloch, D. A., McShane, D. J., Fries, J. F., Cooper, N. S., Healey, L. A., Kaplan, S. R., Liang, M. H., Luthra, H. S., "The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis", <i>Arthritis &amp; Rheumatism</i> , 1988 31(3) pp 3 15-24.
ad	Arnett, F. C., Hamilton, R. G., Roeber, M. G., Harley, J. B., Reichlin, M., "Increased frequencies of Sm and nRNP autoantibodies in American blacks compared to whites with systemic lupus erythematosus", <i>Journal of Rheumatology</i> , 1988 15(12) pp 1773-6.
ae	Bloom, D. D., Davignon, J. L., Cohen, P. L., Elsenberg, R. A., Clarke, S. H., "Overlap of the anti-Sm and anti-DNA responses of MRL/Mp-lpr/lpr mice", <i>Journal of Immunology</i> , 1993 150(4) pp 1579-90.
af	Brahms, H., Raker, V. A., van Venrooij, W. J., Luhrmann, R., "A major, novel systemic lupus erythematosus autoantibody class recognizes the E, F, and G Sm snRNP proteins as an E-F-G complex but not in their denatured states", <i>Arthritis &amp; Rheumatism</i> , 1997 40(4) pp 672-82.
ag	Brahms, H., Raymackers, J., Union, A., de Keyser, F., Meheus, L., Luhrmann, R., "The C-terminal RG dipeptide repeats of the spliceosomal Sm proteins D1 and D3 contain symmetrical dimethylarginines, which form a major B-cell epitope for anti-Sm autoantibodies", <i>J Biol Chem</i> , 2000 275(22) pp 17 122-9.
ah	Brahms, H., Meheus, L., De Brabandere, V., Fischer, U., Luhrmann, R., "Syrnmetrical dimethylation of arginine residues in spliceosomal Sm protein B/B and the Sm-like protein LSm4, and their interaction with the SMN protein", <i>Rna-A Publication of the Rna Society</i> , 2001 7 (11) pp 1531-1542.
ai	Sabbatini, A., Bombardieri, S., Migliorini, P., "Autoantibodies from patients with systemic lupus erythematosus bind a shared sequence of SmD and EpsteinBarr virus-encoded nuclear antigen EBNA 1", <i>European Journal of Immunology</i> , 1993 23(5) pp 1146-52.
aj	Sabbatini, A., Doicher, M. P., Marchini, B., Bombardieri, S., Migliorini, P., "Mapping of epitopes on the SnID molecule: the use of multiple antigen peptides to measure autoantibodies in systemic lupus erythematosus", <i>Journal of Rheumatology</i> , 1993 20(10) pp 1679-83.
ak	Seraphin, B., "Sm and Sm-like proteins belong to a large family: identification of proteins of the U6 as well as the U1, U2, U4 and U5 snRNPs", <i>Embo J</i> , 1995 May 1 14(9) pp 2089-98.
al	Tan, E. M., Kunkel, H. G., "Characteristics of a soluble nuclear antigen precipitating with sera of patients with systemic lupus erythematosus", <i>Journal of Immunology</i> , 1966 96(3) pp 464-7 1.
am	Tan, E. M., Cohen, A. S., Fries, J. F., Masi, A. T., McShane, D. J., Rothfield, N. F., Schaller, J. G., Talal, N., Winchester, R. J., "The 1982 revised criteria for the classification of systemic lupus erythematosus", <i>Arthritis &amp; Rheumatism</i> , 1982 25(11) pp 1271-7.
an	von Muhlen, C. A., Tan, E. M., "Autoantibodies in the diagnosis of systemic rheumatic diseases", <i>Seminars in Arthritis &amp; Rheumatism</i> , 1995 24(5) pp 323-5 8.
ao	Ou, Y., Sun, D., Sharp, G. C., Hoch, S. O., "Screening of SLE sera using purified recombinant Sm-D1 protein from a baculovirus expression system", <i>Clinical Immunology &amp; Immunopathology</i> , 1997 83 (3) pp 3 10-7.
ap	Zhang, W., Reichlin, M., "IgM anti-A and D SnRNP proteins and IgM anti-dsDNA are closely associated in SLE sera", <i>Clinical Immunology &amp; Immunopathology</i> , 1995 74(1) pp 70-6.
aq	Anonymous, "Preliminary criteria for the classification of systemic sclerosis (scieroderma). Subcommittee for scieroderma criteria of the American Rheumatism Association Diagnostic and Therapeutic Criteria Committee", <i>Arthritis &amp; Rheumatism</i> , 1980 23(5) pp 58 1-90.

**FORM PTO - 1449**  
**LIST OF PATENTS AND PUBLICATIONS**  
**FOR APPLICANT'S INFORMATION**  
**DISCLOSURE STATEMENT**

**ATTY DOCKET:** 25401-42  
**APPLICANT:** Michael Mahler  
**FILING DATE:** September 30, 2005  
**FOR:** Analytical Method and Kit Thereof

**SERIAL NO.:** 10/551,636  
**GROUP:**

**OTHER ART (INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)**

ar	Mahler, M, Mierau, R, Schiumberger, W, Bluthner, M., "A population of autoantibodies against a centromere-associated protein A major epitope motif cross-reacts with related cryptic epitopes on other nuclear autoantigens and on the Epstein-Barr nuclear antigen 1", <i>Journal of Molecular Medicine</i> , 2001 79(12) pp 722-3 1.
as	Marchini, B, Doicher, M. P, Sabbatini, A, Klein, G, Migliorini, P., "Immune response to different sequences of the EBNA 1 molecule in Epstein-Barr virus-related disorders and in autoimmune diseases", <i>Journal of Autoimmunity</i> , 1994 7(2) pp 179-9 1.
at	McClain, M. T, Ramsland, P. A, Kaufman, K. M, James, J. A., "Anti-sm autoantibodies in systemic lupus target highly basic surface structures of complexed spliceosomal autoantigens", <i>Journal of Immunology</i> , 2002 168(4) pp 2054-62.
au	Panush, R. S, Edwards, N. L, Longley, S, Webster, E., "'Rhupus' syndrome", <i>Archives of Internal Medicine</i> , 1988 148(7) pp 1633-6.
av	Reichlin, M, Martin, A, Taylor-Albert, E, Tsuzaka, K., Zhang, W., Reichlin, M. W., Koren, E., Ebling, F. M., Tsao, B., Hahn, B. II, "Lupus autoantibodies to native DNA cross-react with the A and D SnRNP polypeptides", <i>J Clin Invest</i> , 1994 Jan 93(1) pp 443-9.
aw	Riemekasten, G, Marell, J, Trebeljahr, G, Klein, R, Hausdorf, G, Haupi, T., Schneider-Mergener, J., Burmester, G. R., Hiepe, F., "A novel epitope on the C-terminus of SmD1 is recognized by the majority of sera from patients with systemic lupus erythematosus", <i>J Clin Invest</i> , 1998 Aug 15 102(4) pp 754-63.
ax	Riemekasten, G., Kawald, A., Weiss, C., Meine, A., Marell, J., Klein, R., Hocher, B., Meisel, C., Hausdorf, G., Manz, R., Kamradt, T., Burmester, G. R., Hiepe, F., "Strong acceleration of murine lupus by injection of the SmD1(83-1 19) peptide", <i>Arthritis &amp; Rheumatism</i> , 2001 44(10) pp 2435-45.
ay	Rokeach, L. A., Haselby, J. A., Hoch, S. O., "Molecular cloning of a cDNA encoding the human Sm-D autoantigen", <i>Proc Natl Acad Sci U S A</i> , 1988 Jul 85(13) pp 4832-6.
az	Rokeach, L. A., Jannatipour, M, Haselby, J. A. Hoch, S. O., "Mapping of the immunoreactive domains of a small nuclear ribonucleoprotein-associated Sm-D autoantigen", <i>Clinical Immunology &amp; Immunopathology</i> , 1992 65(3) pp 3 15-24.
ba	Rokeach, L. A., Hoch, S. O., "B-cell epitopes of Sm autoantigens", <i>Molecular Biology Reports</i> , 1992 16(3) pp 165-74.
bb	De Keyser, F., Hoch, S. O., Takei, M., Dang, H., De Keyser, II., Rokeach, L. A., Talal, N, "Cross-reactivity of the B/B' subunit of the Sm ribonucleoprotein autoantigen with proline-rich polypeptides", <i>Clinical Immunology &amp; Immunopathology</i> , 1992 62(3) pp 285-90.
bc	Gausepohl, fl., Behn, C., "Automated synthesis of solid —Phase bound peptides. In "Peptides arrays on membrane supports, synthesis and applications", J Koch and M. Mahler, Eds, pp 55-68, Springer Verlag, Heidelberg, New York, 2002.
bd	Greidinger, E. L., Hoffman, R. W., "The appearance of U1 RNP antibody specificities in sequential autoimmune human antisera follows a characteristic order that implicates the U1-70 kd and B'fB proteins as predominant U1 RNP immunogens", <i>Arthritis &amp; Rheumatism</i> , 2001 44(2) pp 368-75.
be	Hirakata, M., Craft, J., Hardin, J. A., "Autoantigenic epitopes of the B and D polypeptides of the U 1 snRNP. Analysis of domains recognized by the Y12 monoclonal anti-Sm antibody and by patient sera", <i>Journal of Immunology</i> , 1993 150 (8ptl) pp 3592-60 1.
bf	Hoch, S. O., Eisenberg, R. A., Sharp, G. C., "Diverse antibody recognition patterns of the multiple Sm-D antigen polypeptides", <i>Clinical Immunology</i> , 1999 92(2) pp 203-8.
ag	Hoch, S. O., "The Sm antigens. In "Manual of biological markers of disease", R.N. Maini and W. J. van Venrooij, Eds, pp B2.4/1-29, Kluwer Academic, Dordrecht, The Netherlands, 1994.
ah	Jaekel, H. P., Klöpsch, T., Benkenstein, B., Grobe, N., Baldauf, A., Schoessler, W., Werle, E., "Reactivities to the Sm autoantigenic complex and the synthetic SmD1-aa83-119 peptide in systemic lupus erythematosus and other autoimmune diseases.", <i>Journal of Autoimmunity</i> , 2001 17(4) pp 347-54.
ai	James, J. A., Kaufman, K. M., Farris, A. D., Taylor-Albert, E., Lehman, T. J., Harley, J. B., "An increased prevalence of Epstein-Barr virus infection in young patients suggests a possible etiology for systemic lupus erythematosus", <i>J Clin Invest</i> , 1997 Dec 15 100(12) pp 3019-26.
aj	Lehmeier, T., Raker, V., Hermann, H., Luhrmann, R., "cDNA cloning of the Sm proteins D2 and D3 from human small nuclear ribonucleoproteins: evidence for a direct D1-D2 interaction", <i>Proc Natl Acad Sci U S A</i> , 1994 Dec 6 91(25) pp 123 17-21.
ak	Lerner, M. R., Boyle, J. A., Mount, S. M., Wolin, S. L., Steitz, J. A., "Are snRNPs involved in splicing?", <i>Nature</i> , 1980 283 (5743) pp 220-4.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1221974v1